



Authorities confirm safety of Bisphenol A-based consumer products

Bisphenol A (BPA) has been the subject of extensive scientific testing and governmental reviews worldwide. International authorities such as the European Commission, the European Food Safety Authority (EFSA), the US Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare have all assessed the comprehensive database on BPA.

Based on the overwhelming weight of evidence, these assessments have consistently concluded that human exposure levels to BPA are low and within the safe limits set by government authorities. Over 50 years of research and extensive use throughout the world provide convincing evidence that products made from materials based on BPA are safe for their intended uses.

The following provides an overview of regulatory assessments and a collection of statements from regulatory authorities in Europe and the world regarding the safety of BPA.



2008, Updated EU Risk Assessment

European Union (EU) Risk Assessment

EU Risk Assessments, conducted under the lead of an EU Member State as rapporteur, are widely recognised as one of the world's most rigorous scientific assessments of a substance's safety. A first risk assessment of BPA was published in 2003. For the update, published in 2008, independent scientific experts from EU Member States considered the scientific database of BPA, including several hundreds of studies that had appeared during recent years.

In the updated EU Risk Assessment (2008) the European Commission and the representatives of the EU Member States identified no concern for consumers from products made from materials based on BPA. In the EU Risk Assessment the whole life cycle of BPA, from its production, processing and use through to the disposal of the final article, is comprehensively evaluated for potential risks to human health and the environment. In its update, the UK Health and Safety Executive acting as rapporteur for the assessment of BPA, focused on recent scientific data that had become available since the last report. This data included the results of large scale multi-generation guideline studies and covered, among other parameters, endocrinicity, low dose effects and neurodevelopment.



Karen Aschberger, European Chemicals Bureau (ECB) 2008:
 “We found that the margin of safety is high enough in relation to consumer exposure of BPA in plastic packaging and, as a result, there is no need for further information, testing or risk reduction measures beyond those which are being applied already.”

Risk Assessment Update:
http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf

European Food Safety Authority EFSA

EFSA is an independent expert body responsible for the assessment of and communication about potential risks associated with the food chain. One of its key tasks is the evaluation of substances which are positively listed for the manufacturing of food contact materials (Directive 2002/72/EC), such as BPA.

2010, EFSA

EFSA aims to complete its current re-assessment of the safety of BPA in July 2010. The updated EFSA opinion will cover both the assessment of recently published new research data on BPA, including a comprehensive study on neuro-developmental parameters, as well as the risk assessments conducted by other countries.

Overview of current EFSA activities re BPA:

www.efsa.europa.eu/en/ceftopics/topic/bisphenol.htm

2009, EFSA

In June 2009, as a response to recently published studies on BPA, EFSA reconfirmed its previous position on BPA: “None of the studies which have so far been published have brought into question EFSA’s previous findings on BPA.”

www.foodproduction-daily.com/Quality-Safety/European-safety-watchdogs-reaffirm-belief-in-safety-of-BPA

2008, updated EFSA opinion

In July 2008, in its updated opinion, EFSA reconfirmed its long-standing position that BPA-based polycarbonate and epoxy food contact products are safe for their intended uses for all age groups, including foetuses and newborns. It noted that the established safe intake level for BPA “provides a sufficient margin of safety for the protection of the consumer, including foetuses and newborns.”

In its re-assessment EFSA explicitly took into account recent data and reviews by other authorities, such as the US NTP, Health Canada, the European Commission’s Joint Research Centre and the Norwegian Scientific Committee for Food Safety. The key focus was on the mechanisms of BPA elimination from the human body: “The conclusions of the Panel are that after exposure to BPA the human body rapidly metabolises and eliminates the substance. ... The Panel concluded that the exposure of the human foetus to BPA would be negligible because the mother rapidly metabolises and eliminates BPA from her body. The scientists also concluded that newborns are similarly able to metabolise and eliminate BPA at doses below 1 milligram per kilogram of body weight per day. This implies that

Summary and full EFSA opinion:

www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902017492.htm

Statement:

www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902017373.htm

newborns could effectively clear BPA at levels far in excess of the TDI of 0.05 mg/kg bw set by the Panel and therefore its 2006 risk assessment remains valid.”

2007, EFSA re-evaluation

In January 2007, EFSA issued its re-evaluation of BPA. The experts assessed nearly 200 studies that had appeared since 2002, including a recently published two-generation study in mice. As a result of the strength of the new scientific evidence, EFSA set the permanent TDI at 0.05 milligrams per kilogram of bodyweight, representing an increase of a factor of five compared to the previous temporary TDI set in 2002 by the SCF (the predecessor to EFSA). On low dose effects, the EFSA expert panel concluded “that reports of low-dose endocrine effects of BPA in rodents did not demonstrate such activity in ways that were robust or reproducible”. They also noted that realistic human exposure to BPA via foodstuffs, including that of infants and children, is very low and well below the new TDI.

Abstract:

www.efsa.europa.eu/etc/medialib/efsa/science/afc/afc_opinions/bisphenol_a.Par.0001.File.dat/afc_op_ej428_bpa_op_en.pdf

Summary:

www.efsa.europa.eu/en/scdocs/scdoc/428.htm

Statement:

www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620835386.htm

European National Assessments



Germany

2010, Bundesinstitut für Risikobewertung BfR

The BfR, as competent authority, was involved in the EFSA re-evaluation, and confirmed the EFSA opinion. In its updated Q&A on BPA in baby bottles and pacifiers (30.1.2007, updated 7.1.2010) the BfR states: “Following careful checking of all the studies, in particular those studies in the low dose range of BPA, the BfR carried out a scientific assessment of the results and came to the conclusion that the presence of BPA in polycarbonate bottles poses no health risk to babies and infants during normal use.”

Q&A on BPA in baby bottles and pacifiers

www.bfr.bund.de/cm/276/ausgewaehlte_fragen_und_antworten_zu_bisphenol_a_in_baybflaeschen_und_saugern.pdf

2009, Federal German Government

In June 2009, the German government stated in a response to a parliamentary request: “...For hardly any chemical are there as comprehensive and specific toxicological and exposure data, which makes a valid risk assessment possible and an accurate TDI estimation feasible ...”

Statement:

<http://dip21.bundestag.de/dip21/btd/16/131/1613104.pdf>

2008, Bundesinstitut für Risikobewertung BfR

In September 2008, the German Federal Institute of Risk Assessment (Bundesinstitut für Risikobewertung BfR), in response to media articles triggered by recent studies, reconfirmed its previous opinion on the safety of BPA. The BfR assessed whether the studies provided any reason to reconsider the health risk assessment of BPA. It concluded that there was no reason to change their current risk assessment. The

Statement:

www.bfr.bund.de/cm/216/neue_studien_zu_bisphenol_a_stellen_die_bisherige_risikobewertung_nicht_in_frage.pdf

BfR repeated that there is no health risk for consumers if the TDI of 0.05 milligrams of BPA per kilogram of bodyweight established by the EFSA in 2007 is observed.



UK

April 2010, Food Standards Agency FSA

In April 2010, Andrew Wadge, chief toxicologist at the FSA, reconfirmed the authority's focus on sound science as basis for safety assessments: "We will always base our advice to consumers on the best available scientific evidence. Independent scientific experts advise that current levels of exposure to BPA are not harmful. The European Food Safety Authority review concluded that low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way, and so cannot be used as pivotal studies for risk assessment."

Link:

www.independent.co.uk/life-style/health-and-families/health-news/scientists-call-for-ban-on-danger-chemical-1938690.html

2009, FSA

In June 2009, as a response to certain studies published on BPA, the UK Food Safety Authority (FSA) confirmed its current position that BPA-based food contact materials can safely be used: "The view of the FSA on BPA has not changed. We do not believe that UK consumers are exposed to levels of BPA that would be considered a danger."

Link:

www.foodproductiondaily.com/Quality-Safety/European-safety-watchdogs-reaffirm-belief-in-safety-of-BPA

2009, UK Government

Also in June 2009, replying to an inquiry from the UK House of Lords, the UK Department of Health reconfirmed that BPA-based food contact materials can be used safely: "... the FSA sees no basis, on the evidence we have, to press for tighter controls on the use of BPA, or for a ban on its use. Limits in place throughout the European Union, which the FSA has played a full part in establishing and maintaining, provide a precautionary margin of safety beyond expert assessment of the scientific evidence."

Link:

<http://services.parliament.uk/hansard/Lords/ByDate/20090615/writtenanswers/parto21.html>



France

March/April 2010, Agence Francaise de Sécurité Sanitaire des Aliments, AFSSA

During their continuous assessments of new data on BPA the French Food Safety Authority stated in spring 2010: "Various risk assessments carried out by food and health safety authorities have concluded that, based on the available scientific data, there is no risk for the consumers in the current applications." The results of the AFSSA study on French consumer exposure to BPA published in April 2010 confirmed existing data of very low levels and is consistent with the exposure findings in other countries: "The average French consumer exposure to BPA is ca. 1 microgr/kg bw/day. This is 50-100 times below the TDI set by EFSA...". Consequently, there is no need to change eating habits in France. Nevertheless, AFSSA would like to see EFSA to take measures on the European level to further protect consumers and minimise exposure to

Link:

www.afssa.fr

BPA, especially for sensitive subgroups. AFSSA also cooperates with the German BfR and EFSA on developing valid methodologies for a reliable assessment of risks related to endocrine active substances.

2009, French Government

Referring to concerns raised by some media and non-governmental organisations, the French Minister of Health, Roselyne Bachelot-Narquin, confirmed on several occasions during 2009 (March, April, June) that BPA does not represent a health risk: “...recent in-depth studies by the AFSSA and the EFSA concluded that BPA-based baby bottles are harmless. Any residual levels of BPA are significantly below the maximum limits set by health authorities...The precautionary principle becomes applicable when there are no reliable studies. Here (for BPA) these reliable studies are available, and on the basis of the scientific studies confirm no risk [for baby bottles produced with this substance]...”

Protocol:

www.assemblee-nationale.fr/13/cr/2008-2009/20090209.asp#P229_32159

2008, AFSSA

In October 2008, the French Food Safety Authority (AFSSA) re-evaluated BPA in light of recent research and confirmed that BPA poses no risk to human health in food contact applications: “...when the contents of polycarbonate baby bottles are heated in the microwave under realistic conditions (heating time less than 10 minutes), the amounts of bisphenol A transferable to food are very low, and stay far short of the maximum migration value adopted by EFSA for its exposure calculation. Therefore, the conclusions of EFSA’s 2006 opinion still apply to the specific cases of heating polycarbonate baby bottles in the microwave and do not justify any special conditions of use.”

Report:

www.afssa.fr/Documents/MCDA_2008Sa0141.pdf



Spain

April 2010, Agencia Española de Seguridad Alimentaria y Nutrición, AESAN

In the context of the availability of new studies and ongoing assessments of BPA in Europe the Spanish Food Safety Authority said: “Under these circumstances, and taking into account the scientific data and the EFSA recommendation, the Spanish safety authority, like the large majority of the other national safety authorities in Europe, does not think that there is a reason to take any measures with regard to the substance at the moment.”

www.aesan.msc.es/AESAN/web/notas_prensa/bisfenolA.shtml



2009, Bundesamt für
Gesundheit BAG

Switzerland

In February 2009, the Swiss Federal Office of Public Health (BAG) re-evaluated BPA in light of recent research and confirmed that BPA is not a risk to human health when used for food contact applications. BAG also highlighted the potential risks of replacing BPA-based products with less-studied alternatives: “... After evaluating the scientific reports of various food safety authorities the BAG is of the opinion that the intake of bisphenol A from food represents no risk to the consumer. This also applies to newborns and infants. ... A ban on BPA would inevitably cause manufacturers of packaging and consumer products (food contact materials) to have to switch to other substances, the toxicity of which is less well known. This would mean a well characterised risk would be replaced with a conspicuously unpredictable risk.”

Statement:

[www.bag.admin.ch/
themen/lebensmittel/04861/
06170/index.html?lang=de](http://www.bag.admin.ch/themen/lebensmittel/04861/06170/index.html?lang=de)



2008, Voedsel en waren
autoriteit VWA

The Netherlands

In November 2008, the Dutch Food and Consumer Product Safety Authority published their migration study results, and confirmed the safety of BPA-based baby bottles: “The researched polycarbonate baby bottles have no demonstrable migration of BPA into the simulants for fruit juice and milk. This means that the bottles are safe for use for babies and toddlers with respect to BPA.”

Statement:

[www.vwa.nl/actueel/
bestanden/fileitem/31842](http://www.vwa.nl/actueel/bestanden/fileitem/31842)



2009, Belgian
Government

Belgium

In June 2009, the Belgian Health Minister, Laurette Onkelinx, confirmed in the Belgian Parliament that no additional measures for BPA are needed: “In its last report issued on 22 October 2008, EFSA took the latest studies into consideration as well as more than 650 other studies dealing with BPA. Conclusions clearly indicate that safety criteria currently applied in the EU are largely sufficient to ensure the safety of consumers, even the weakest ones. ... The results of the analyses of AFSCA (Belgian Food Safety Agency) ... show that all values measured were far inferior to the migration limits. ... Based on these conclusions and data, no complementary measure is envisaged, either at EU or Member State level ...”

Protocol:

[www.lachambre.be/
doc/CCRI/pdf/52/ic575.pdf](http://www.lachambre.be/doc/CCRI/pdf/52/ic575.pdf)



Denmark

March 2010, Danish Minister for Food, Agriculture and Fisheries

On 26.3.2010, in conflict with the currently enforced “European Directive on Plastics in Contact with Food”, Denmark announced a temporary national ban on BPA-based food contact materials in products intended for children aged 0-3, referring to the Danish assessment of a recent comprehensive neuro-developmental study that “did not fully close knowledge gaps raised by other studies”. In contrast, the U.S. Food and Drug Administration (FDA), with respect to the same study, confirmed the authors’ conclusion that BPA is not a developmental neurotoxicant. The legal implications of the Danish decision in view of European trade and food law will have to be awaited.

Press release of Danish Food Minister :

www.fvm.dk/Default.aspx?ID=18488&PID=169747&NewsID=6014

Assessment of FDA:

www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0100 (under supporting & related material)

2008, Folketinget, Danish Environmental Protection Agency

In November 2008, the Danish Environmental Protection Agency re-evaluated BPA in light of recent research and confirmed that BPA is not a risk to human health in food contact applications: “[The Environment Protection Agency has in the light of this assessment concluded that these studies do not alter the decision in the EU assessment. It is therefore concluded that the differences in data for assessments in the EU and in particular the United States and Canada do not have any bearing on the overall assessment of bisphenol A.](#)”



Ireland

2009, Food Safety Authority

In June 2009, Rhodri Evans, the Chief Specialist in Toxicology with the Irish Food Safety Authority, confirmed that BPA-based food contact materials can be safely used: “[The advice is that there’s no need to avoid BPA.](#)”

www.independent.ie/health/battle-of-the-bottles-1783079.html



USA

January 2010, Food and Drug Administration FDA

On January 15, 2010, the US Food and Drug Administration (FDA) in their updated position on BPA found no evidence of harm to children or adults from the current levels of BPA-exposure, and at the same time provided guidance on how parents can minimise infant exposure to BPA if they choose to do so. The statement included their assessment of a recently published comprehensive neuro-developmental study: FDA concluded that there is no evidence that BPA is a developmental neurotoxicant at any dose tested. FDA stated that “[Studies employing standardised toxicity tests have thus far supported the safety of current low levels of human exposure to BPA.](#)” FDA shares the “some concern” about potential effects of BPA based on studies using novel approaches to test for subtle effects, which had been stated by

Overview and current position of FDA:

www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm#current

Information for parents from US Dpt Human Health Services:

www.hhs.gov/safety/bpa/

	FDA/NHIES in 2008. This will be addressed by a specific FDA research program which is already ongoing. In a media news briefing, Dr. Joshua Sharfstein, the principal deputy commissioner of the drug agency, stated “if we thought it was unsafe, we would be taking strong regulatory action”.	Statement of Sharfstein, FDA: www.nytimes.com/2010/01/16/health/16plastic.html
2009, State of California	In July 2009, the scientific expert panel of the Californian Office of Environmental Health Hazard Assessment (OEHHA, an Office of the Californian Environmental Protection Agency) concluded that BPA is not a reproductive or developmental toxicant. In a public meeting, the panel voted unanimously not to list BPA under Proposition 65 (a list of chemicals believed to have hazardous effects).	www.oehha.ca.gov/prop65/public_meetings/darto71509synop.html
2008, BPA assessment FDA	In August 2008, the US FDA published its draft assessment on the safety of BPA in food contact materials. The US authority “concluded that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses.” In its statement following the release of the Science Subcommittee’s report at the end of October 2008, whilst confirming that it is undertaking further analysis of BPA, the FDA clearly states that “[B]ased on all available evidence, the present consensus among regulatory agencies in the United States, Canada, Europe, and Japan is that current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and babies.”	Report: www.fda.gov/ohrms/dockets/AC/o8/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf
		
March 2010, Government of Canada	Despite Health Canada’s science-based conclusion that “Science tells us that exposure levels are below levels that could cause health effects”, in March 2010 the Canadian government enforced a ban on the importation, sale and advertising of polycarbonate baby bottles in Canada, and works to develop and implement codes of practice to reduce levels of BPA in infant formula as low as reasonably achievable.	Overview and further docs: www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/index-eng.php
2009, Health Canada migration studies	In March and July 2009, Health Canada published four studies that investigated migration of BPA into bottled water, baby food, powdered infant formula and canned soda. All studies strongly re-confirm that migration levels are extremely low, and the use of the products is safe. “The contribution of BPA levels in bottled water to the overall exposure is negligible for the general population, and the consumption of water from polycarbonate carboys does not pose a safety concern”. No BPA was detected in any of the canned powdered infant formula samples	Canned Soda: www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/securit/bpa_survey-enquete-can-eng.pdf Bottled Water: www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/bpa_survey-summ-enquete-bot-bou-eng.php

tested. The level of BPA found in baby food packaged in jars clearly indicates that exposure to BPA is extremely low and much lower than the tolerable life long daily intake set in Canada. Health Canada notes that “the nutritional benefits of baby food products far outweigh any possible risk”. For canned soda Health Canada stated that “an adult would have to consume app. 940 canned drinks in one day to approach the provisional TDI set by Health Canada.”

2009, Health Canada

Canada plans to restrict the use of BPA-based materials in food contact applications for small children. Regarding these plans, the French Minister of Health, Roselyne Bachelot-Narquin, stated: “The Canadian authorities decided on the ban on BPA as a result of public pressure not on the basis of valid scientific studies. The precautionary principle is a rational principle, not an emotional one.”

Canada states itself in the Canada Gazette in June 2008: “The final screening assessment confirmed that exposure levels for bisphenol A are below those that could cause health effects in the general population. ... Although bisphenol A exposure levels in newborns and infants is below that which could cause health effects based on animal studies, it is considered appropriate to apply a precautionary approach when characterizing risk to health of this susceptible subpopulation.” (Canada Gazette, 27 June 2009)

2008, Health Canada Risk Assessment

In October 2008, Health Canada published its final Screening Risk Assessment of BPA. It concludes that the “general public need not be concerned” by exposure to BPA. “Bisphenol A does not pose a risk to the general population, including adults, teenagers and children. Therefore, consumers can continue to use polycarbonate water bottles and consume canned foods and beverages, as the level of exposure from these products is very low. As well, consumers can continue to use tableware and storage containers made of polycarbonate.”



2010, Food Standards Australia New Zealand FSANZ

January 2010: “FSANZ has assessed the studies that led to the USFDA decision to undertake a review and further research, and our view remains that BPA in baby bottles and food packaging in Australia and New Zealand is still safe. For example our dietary modelling shows that a 5 kg baby would need to drink around 80 bottles of formula a day every day for many years before it would get up to the safety limit.” In the same statement, FSANZ confirmed what other regulatory authorities also noted: “BPA does not cause cancer.”

Baby Food:

www.hc-sc.gc.ca/fn-an/securit/packag-embal/bpa/bpa_survey-summ-enquete-eng.php

Infant Formula:

www.hc-sc.gc.ca/fn-an/securit/packag-embal/bpa/bpa_survey-summ-enquete-pow-pou-eng.php

Protocol:

http://www.assemblee-nationale.fr/13/cri/2008-2009/20090209.asp#P229_32159

<http://www.gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

Health Canada BPA fact sheet 17.10.08:

www.chemical-substanceschimiques.gc.ca/challenge-defi/bisphenol-a_fs-fr_e.html

Risk assessment report:

www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_167-eng.php

www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2010/bisphenolabpaandfood4701.cfm



**2005, Ministry of
Economy, Trade and
Industry METI Risk
Assessment**

Japan

In November 2005, the Japanese National Institute of Advanced Industrial Science and Technology (AIST), one of the administration agencies of the Japanese Ministry of Economy, Trade and Industry (METI), finalised its risk assessment of BPA. The Institute concluded “... that the current exposure levels of BPA will not pose any unacceptable risk to human health” and disregarded the low dose hypothesis since “the findings in the low dose studies were not robust while those in the negative studies were consistent.” The Japanese Ministries saw no need for further statements on BPA.

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